

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

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|--------------|--|------------------|---------|
| Applicant(s) | : Dudley <i>et al.</i>   | Customer No.     | : 11030 |
| Serial No.   | : 10/829,618   | Confirmation No. | : 7286  |
| Filed        | : 4/20/2004  | Group Art Unit   | : 1627  |
| Examiner     | : Jean-Louis, Samira   |                  |         |
| For          | : Androgen Pharmaceutical Composition and Method for Treating Depression |                  |         |

**SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

Applicants hereby submit the present Supplemental Information Disclosure Statement in the application noted above.

Enclosed herewith for consideration by the U.S. Patent and Trademark Office are publicly available materials related to prior and ongoing litigations involving one or more cases related to the above-identified application. Per the request of the Examiner, Applicants have also identified the patent and non-patent literature references that have been cited during these various litigations separately on the enclosed PTO-1449. It is noted for the convenience of the Examiner that certain of these references were previously submitted for consideration. Additional miscellaneous patents and non-patent references that were uncovered from related files are also provided for consideration.

As required by MPEP 609(b)(3) and 609.04(a), for each of the following documents listed on the attached PTO Form 1449 that is not in the English language, an English abstract or English language translation of that item or a portion thereof or a concise explanation of the relevance of that item is enclosed.

Applicants note for the Examiner that certain confidential and/or proprietary materials will be submitted separately under seal for consideration. Furthermore, additional

documents and materials from the identified litigations are available and will be provided upon the request of the Examiner. Based upon reasonable investigation, Applicants submit that the attached materials are believed to true, complete and accurate copies.

This Information Disclosure Statement is submitted according to the following selected paragraph(s):

- ☒ This Information Disclosure Statement is being filed under 37 C.F.R. §1.97(b) (1) within three months of the filing date of a national application other than a continued prosecution application under 37 C.F.R. § 1.53(d); (2) within three months of the date of entry of the national stage as set forth in 37 C.F.R. § 1.491 in an international application; (3) before the mailing of a first Office action on the merits; or (4) before the mailing of a first Office action after the filing of a request for continued examination under 37 C.F.R. § 1.114.
- ☐ This Information Disclosure Statement is being filed under 37 C.F.R. §1.97(c) prior to either a final action or a notice of allowance. Payment for the fee required by 37 C.F.R. §1.17(p) is hereby authorized to be charged to Deposit Account No. 02-4377.
- ☐ This Information Disclosure Statement is being filed under 37 C.F.R. §1.97(c), with a statement under, 37 C.F.R. §1.97(e) prior to either a final action or a notice of allowance. The undersigned hereby states that (check one):
- ☐ each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement.
- ☐ no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing of the information disclosure statement.

- ☐ This Information Disclosure Statement is being filed under 37 C.F.R. §1.97(d), with a statement under 37 C.F.R. §1.97(e), after a final action or a notice of allowance but prior to payment of the issue fee. Payment for the fee required by 37 C.F.R. §1.17(p) is hereby authorized to be charged to Deposit Account No. 02-4377. The undersigned hereby petitions that this Information Disclosure Statement be considered prior to issuance of the patent. The undersigned hereby states that (check one):
- ☐ each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement.
- ☐ no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing of the information disclosure statement.
- ☐ The references listed on the accompanying PTO-1449 were either cited by the Examiner or previously submitted in parent application U.S. Serial No. \_\_\_\_\_, filed \_\_\_\_\_. Pursuant to 37 C.F.R. § 1.98(d), the references are not required if the earlier application is identified and relied upon for an effective filing date under 35 U.S.C. § 120 and therefore are not enclosed herewith.

**Related Application Disclosure**

- ☐ Applicants would like to bring to the attention of the Examiner the following related patent applications, which are also listed on the accompanying PTO-1449:

**Disclosure of Office Actions and Responses in Related Applications**

- ☒ Applicants would like to bring to the attention of the Examiner the following Office Actions issued in related patent applications and Responses to Office Actions filed in such applications, which are also listed on the accompanying PTO-1449:

10/829618

12-30-2010 Final Rejection

This submission does not represent that a search has been made or that no better art exists and does not constitute an admission that the listed documents are material or constitute "prior art." If the Examiner applies the documents as prior art against any claim in the application and Applicants determine that the cited documents do not constitute "prior art" under United States law, Applicants reserve the right to present to the Office the relevant facts and law regarding the appropriate status of the documents.

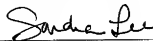
Applicants further reserve the right to take appropriate action to establish the patentability of the disclosed invention over the listed documents, should the documents be applied against the claims of the present application.

Applicants believe no fee is due in connection with this submission. However, if any fee is due, or if any overpayment has been made, the Commissioner is authorized to charge any such fee or credit any overpayment to our Deposit Account No. 02-4377.

Date: January 12, 2011

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Respectfully submitted,



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